

REMARKS

A. Terminal Disclaimer

Without admission that the present claims are obvious in view of the claims of the cited patents of assignee, and to expedite allowance of the present application, a terminal disclaimer is submitted herewith with respect to all patents cited as a basis for double patenting rejection in pages 5–6 of the Office Action.

B. Declaration of Paul J. Buscemi, Ph.D.

In support of this amendment, a declaration is submitted by Paul J. Buscemi, Ph.D. Dr. Buscemi has a doctorate in biomaterials and has many years of experience in research and development in biomaterials with a heavy emphasis in studying and evaluating tissue response (including fibrosis) to implanted materials. Throughout these Remarks, reference is made to various portions of the Buscemi Declaration.

C. Response to Rejections

a. Cancellation of Apparatus Claims

Without prejudice to Applicants' rights to filing continuation applications with such claims, apparatus claims 7–10 are cancelled.

b. Remarks Pertaining to Rejection of Method Claims

Claim 1 was rejected solely (except for double patenting noted above) as being anticipated by U.S. Pat. No. 5,979,456 to Magovern. In response to the rejected, Applicants have substantively amended claim 1 in a manner to clearly distinguish Magovern.

c. U.S. Pat. No. 5,979,456 ("Magovern")

Magovern was cited to reject all claims. Of these, claim 1 is independent. This claims is amended to more clearly distinguish over Magovern to expedite allowance. These amendments include reciting the implant is a passive implant acting without application of external energy. Further, relevant amendments include identifying the material of the implant inducing a fibrotic response of material amount.

i. Magovern Requires Activation By An Energy Source to Alter Physiology

The Examiner has directed Applicants' attention to the embodiments of Figs. 8 – 10 of Magovern. The Examiner will recognize that Magovern is an active implant which only functions when activated. This activation is heating or cooling to alter the crystalline structure of the material of Magovern. (Buscemi Declaration, ¶ 5.b.).

Independent claim 1 is amended to clearly recite the alteration of tissue response is passive and does not require an activation force.

ii. Magovern Does Not Teach A Material Which Imparts A Fibrotic Sufficient When Combined With Passive Mechanical Stiffness to Alter Physiology

Applicants note the present claims recite the fibrotic response is sufficient, in combination with the passive mechanical characteristics (e.g., stiffness) of the implant, to alter tissue response to airflow. In Magovern, the implanted device only affects physiology when activated by an energy source. Neither the passive material qualities, any fibrotic response, nor any combination of mechanical stiffness and fibrosis is adequate in Magovern to alter tissue stiffness. (Buscemi Declaration, ¶ 5.c and 5.d).

The implants of Magovern are described as one or more suture-like threads of shape-memory material inserted into musculature. (Magovern, col. 7, lines 56 – 59). The shape-memory material is described in column 5, lines 48 – 56. Suture-like threads of such material in musculature do not have a significant fibrotic response. Furthermore, such materials are highly compliant such that the material strength and any miniscule fibrotic response would not alter tissue response to airflow. (Buscemi Declaration, ¶ 5.c and 5.d).

D. Supplemental Information Disclosure Statement

Submitted herewith is a supplemental Information Disclosure Statement citing the Ersek article which was cited in a related application. It is believed the teachings of Ersek are no more material than those already considered by the Examiner.


E. Conclusion

Applicants submit this application is now in condition for allowance. Reconsideration and Notice of Allowance are solicited. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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